

# Multi-center, single-arm study to assess the safety, efficacy, discontinuation rate and pharmacokinetics of the low-dose levonorgestrel intrauterine contraceptive system (LCS12) in post-menarcheal female adolescents under 18 years of age for 1 year, and an optional 2-year extension phase

Published: 28-07-2011

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40073

### Source

ToetsingOnline

### Brief title

LCS12 adolescent study

### Condition

- Other condition

**Synonym**

intrauterine system as a contraceptive, prevention of pregnancy

**Health condition**

intrauterine anticonceptie

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Bayer

**Source(s) of monetary or material Support:** Bayer Healthcare AG

**Intervention**

**Keyword:** adolescent, contraception, intrauterine

**Outcome measures****Primary outcome**

1) Number of adverse events reported by study subjects 2) Portion of subjects reporting adverse events

**Secondary outcome**

1) Overall satisfaction rating from 1 to 5 (from very satisfied to very dissatisfied)

2) Pearl Index

3) Bleeding patterns collected from patients' diary

4) Concentration of levonorgestrel in serum

5) Concentration of sex hormone binding globulin in serum

6) Discontinuation rate

## Study description

### Background summary

Safety of LCS12 in adolescents according to by EMA approved Paediatric Investigational Plan

### Study objective

The study will assess the safety of a sex hormone (levonorgestrel) releasing T-shaped intrauterine contraceptive system in female adolescents under 18 years of age. The incidence of adverse events over 12 month treatment period will be the main outcome of this study. Also the efficacy (number of pregnancies), discontinuation rate and pharmacokinetics will be evaluated.

### Study design

Non-exploratory trial

### Intervention

LCS12 insertion into the uterus at insertion visit 2 with the study treatment of 12 months. An optional follow up phase up to 2 years will be offered for all subjects completing 12 month treatment time.

### Study burden and risks

Risk to be found at section E9.

Burden: 7-9 visits, daily completion of an electronic diary during the first year, blood (max 4) and urine samples (7-9) and cervical smear (once). Gynaecologic examination, including breast palpitation (7-9 times) and a general physical examination (2-4 times)

## Contacts

### Public

Bayer

Energieweg 1  
Mijdrecht 3641 RT  
NL

### Scientific

Bayer

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)

Adolescents (16-17 years)

### **Inclusion criteria**

- The subject has signed and dated the informed consent form.
- The subject is a female adolescent, generally healthy, post-menarcheal, nulliparous or parous requiring contraception and is under 18 years of age at screening visit.
- The subject has regular menstrual cycles without hormonal contraceptive use (at regular intervals of 21-35 days).
- In the opinion of the investigator, the subject has general and uterine conditions suitable for the insertion of LCS12 (uterine sound depth 6-10cm).
- The subject has clinically normal safety laboratory results.
- The subject has a normal or clinically insignificant cervical smear (i.e. one that does not require further follow up according to Bethesda or a comparable system).
- The subject is willing and able to attend the scheduled study visits and to comply with the study procedures

### **Exclusion criteria**

- Known or suspected pregnancy or is lactating.
- Vaginal delivery, cesarean delivery, or abortion less than 6 weeks before Visit 1.
- Historic of ectopic pregnancies.
- Infected abortion or postpartum endometritis less than 3 months before Visit 1.
- Abnormal uterine bleeding of unknown origin.
- Any lower genital tract infection (until successfully treated).
- Acute or history of recurrent pelvic inflammatory disease.
- Congenital or acquired uterine anomaly.

## Study design

### Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2011
Enrollment:	96
Type:	Actual

### Medical products/devices used

Product type:	Medicine
Brand name:	LCS12
Generic name:	nvt

## Ethics review

Approved WMO	
Date:	28-07-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	12-09-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	01-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	07-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	22-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	24-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	25-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	19-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

Approved WMO

Date: 25-06-2012

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 21-09-2012

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 28-09-2012

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 18-09-2014

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 26-09-2014

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

EudraCT

CCMO

### ID

EUCTR2011-002065-37-NL

NL37467.060.11